

REMARKS

The present application is directed to pharmaceutical compositions containing combinations of an antibody and antibody fragment, combinations of antibody fragments, and methods of treatment using the compositions for various conditions, particularly conditions caused by toxins such as botulism.

Claims 1-18 are currently pending in the application. Claims 19 and 21 were previously withdrawn, and Claims 20 and 22 were previously cancelled. Claims 1, 2, 4, 6, 7, 8, 9, 18, and 21 are currently amended. Support for the amendments can be found at least on page 4, line 11, to page 5, line 2, of the specification. No new matter has been added.

Withdrawn Rejections

Applicants gratefully acknowledge the Examiner's withdrawal of all grounds of rejection from the Office Action mailed September 24, 2007.

Rejection under 35 U.S.C. §112, second paragraph

In the Office Action mailed May 12, 2008, the Examiner rejected Claim 4 under 35 U.S.C. §112, second paragraph, as indefinite. Applicants respectfully traverse the rejection.

The Examiner requested clarification regarding an antibody classified as "IgT". It is known by those skilled in the art that IgT is an Ig heavy chain isotype found in some fish, including rainbow trout. In support of this assertion, applicants enclose as Exhibit A an article by Hansen *et al.* (Discovery of a unique Ig heavy-chain isotype (IgT) in rainbow trout: Implications for a distinctive B cell developmental pathway in teleost fish, *Proc. Natl. Acad. Sci., USA*, 2005, 102, 19, 6919-6924).

Consequently, applicants respectfully submit that the metes and bounds of an antibody classified as IgT are clear and request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §101

The Examiner rejected Claims 1-18 under 35 U.S.C. §101 as directed to non-statutory subject matter. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 1 has been amended to clarify that, if the first specific binding agent is an antibody, that antibody is an **isolated** antibody. The term “isolated antibody” was suggested by the Examiner in the Office Action mailed May 12, 2008. Claims 2-18 depend either directly or indirectly from Claim 1 and are subject to the amendments made therein.

Furthermore, applicants respectfully submit that neither large binding fragments nor small binding fragments of an antibody are naturally occurring; they may be produced as described on page 4, lines 26-32 of the specification through chemical treatment of isolated antibodies.

For at least the reasons set forth above, applicants respectfully assert that the rejection under 35 U.S.C. §101 has been overcome and request its withdrawal.

Rejection under 35 U.S.C. §102(b)

In the Office Action mailed May 12, 2008, the Examiner rejected Claims 1-18 under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Habermann *et al.* (*Med. Microbiol. Immunol.* Vol. 161, pp. 203-210, 1975; hereinafter “Habermann”). Applicants respectfully traverse the rejections.

Habermann describes an antitoxin containing antibodies against botulinum toxins A, B, and E.

Applicants respectfully submit that Habermann fails to teach a composition containing the combination of an antibody and a **fragment** of an antibody or a composition including the combination of two antibody **fragments**. In addition, Habermann fails to teach a composition having binding agents that bind to the **same** toxin.

Consequently, Habermann fails to disclose each and every element of, and therefore fails to anticipate, Claims 1-18. For at least the foregoing, applicants respectfully

assert that the rejection under 35 U.S.C. §102(b) has been overcome and request its withdrawal.

With regard to the alternative rejection, under 35 U.S.C. §103(a), applicants submit that Habermann fails to teach, suggest or imply a composition having **fragments** of an antibody because Habermann discloses a composition containing **intact natural** antibodies. Furthermore there is no teaching, suggestion, or implication by Habermann to provide a composition containing two binding agents that bind to the **same** toxin. Habermann discloses only a composition containing binding agents to **different** toxins.

For at least these reasons, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

This response fully addresses the rejections in the Office Action mailed May 12, 2008. In light of the above remarks, applicants respectfully assert that the application is now in condition for allowance. Such action is respectfully requested.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or if there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 745-2473 is respectfully solicited.

No additional fees are believed due; however the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account number 11-0855.

Respectfully submitted,

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